ATTACHMENT 3

510(K) SUMMARY OF SAFETY & EFFECTIVENESS

Official Contact	David J. Vanella Manager, Regulatory Affairs/Product Assurance Respironics, Inc. 1001 Murry Ridge Lane Murrysville, PA 15668
Classification Reference	21 CFR 868.5905
Product Code	BZD – Non-Continuous ventilator
Common/Usual Name	CPAP/Bi-level System
Proprietary Name	Respironics BiPAP® Duet® LX Bi-level System
Predicate Device(s)	Respironics BiPAP® Duet® System (K964363) Respironics Virtuoso® LX Smart CPAP System (K993433)
Reason for submission	Modified design, additional accessories.

Substantial Equivalence

The modified device has the following similarities to the previously cleared predicate device:

- ❑ Same intended use.
- ❑ Same operating principle.
- ❑ Same technology.
- ❑ Same manufacturing process.

Design verification tests were performed on the BiPAP® Duet® LX Bi-level System as a result of the risk analysis and product requirements. All tests were verified to meet the required acceptance criteria. Respironics has determined that the modifications have no impact on the safety and effectiveness of the device. In summary, the device described in this submission is substantially equivalent to the predicate device.

The modified device complies with the applicable standards referenced in the Guidance for FDA Reviewers and Industry "Guidance for the Content of premarket Submissions for Software Contained in Medical Devices", May 1998.

Intended Use

The BiPAP® Duet® LX Bi-level System delivers positive airway pressure therapy for the treatment of Obstructive Sleep Apnea only for use in the home or hospital/institutional environment on adult patients.

Device Description

The BiPAP® Duet® LX Bi-level System is a microprocessor controlled blower based bi-level positive pressure system that delivers two different positive pressure levels (IPAP/EPAP). The dual pressure levels provide a more natural means of delivering pressure support therapy to the patient resulting in improved patient comfort. The Auto-Trak Sensitivity™ feature of the BiPAP® Duet® LX Bi-level System ensures a breath-by-breath response to the patient's breathing patterns and circuit leaks, providing comfortable support with every breath. The BiPAP® Duet® LX Bi-level System is intended for use with a patient circuit that is used to connect the device to the patient interface device (mask). A typical patient circuit consists of a six-foot disposable or reusable smooth lumen 22mm tubing, an exhalation device, and a patient interface device.

The BiPAP® Duet® LX Bi-level System incorporates the use a SmartCard™. The SmartCard™ is a credit card-size data recorder that is inserted or removed from the side of the BiPAP® Duet® LX Bi-level System. The card data is transacted via a SmartCard™ reader that is part of a home care provider or physicians data

management system. The SmartCard™ provides a secure means for data collection and transfer between the patient and the home care provider or physician.

The SmartCard™ records device usage data from BiPAP® Duet® LX Bi-level System for evaluation by the Home Care Provider and/or physician, at their offices, to monitor patients who suffer from Obstructive Sleep Apnea. Each SmartCard™ for a patient is unique, in that all aspects of a patient's prescription can be programmed onto the SmartCard™. The data obtained from a SmartCard™ consists of device information that the Home Care Provider can access. Currently, the only means available to obtain patient data is for the Home Care Provider to get direct access to the patient's device and download the device information directly via RS232. An external modem may also be used, via the RS232 interface for data download, if required.

A SmartCard™ can also be used to transfer new or updated prescriptions to the patient's device. Periodically, a prescription may change for various reasons. Currently, the process for changing or setting up a prescription is for the Home Care Provider to visit the patient and manually adjust the device. With the use of a SmartCard™, the prescription may be changed by inserting the SmartCard™ into the unit, which eliminates the need for the Home Care Provider to be present to change the prescription pressure settings or the modes of operation.

The Encore Data Management Software is a tool for managing device data using a personal computer. The compliance data that is stored on a SmartCard™ is downloaded into an Encore file though the use of a SmartCard™ Reader. Once the data is uploaded, the Encore Data Management Software uses this data to display a graphical and statistical analysis of the data for use by the clinician and home care provider to assess patient compliance, maintain a patient's therapeutic history or analyze a prescription setting. The Encore Data Management Software does not perform any automatic scoring or diagnosing of a patient's therapy data.

When prompted by the Home Care Provider, the patient can access the BiPAP® Duet® LX Bi-level System menu to answer specific questions regarding their quality of life. The written questions are included with the device packaging for the patient to read. The answers to the questionnaire are entered via the BiPAP® Duet® LX device keypad and stored on the SmartCard™ for later download. The purpose of the questionnaire is to determine if therapy has improved a patient's quality of life, as well as how treatment promotes the return to wellness. Currently, the Home Care Provider sends the patient a copy of the FOSQ to manually complete and return.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 22 2000

Mr. David J. Vanella
Respironics, Inc.
1001 Murry Ridge Lane
Murrysville, PA 15668-8550

Re: K000994
BiPAP® Duet® LX Bi-Level System
Regulatory Class: II (two)
Product Code: 73 BZD
Dated: May 19, 2000
Received: May 22, 2000

Dear Mr. Vanella:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597, or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for Mark N Melkerson

James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K000994

Device Name: Respironics® BiPAP® Duet® LX Bi-level System

Intended Use/Indications for Use

The BiPAP® Duet® LX Bi-level System delivers positive airway pressure therapy for the treatment of Obstructive Sleep Apnea only.

Environment of Use/Patient Population

For use in the home or hospital/institutional environment on adult patients.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use

(Per 21 CFR 801.109)

(Optional Format 1-2-96)

for Mark N Melkerson

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K000994